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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,732

05/17/2007

Andrew Ian Cooper

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201 7590 06/03/2010  
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EXAMINER

NEGRELLI, KARA B

ART UNIT

PAPER NUMBER

1796

NOTIFICATION DATE

DELIVERY MODE

06/03/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentgroupus@unilever.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/587,732	<b>Applicant(s)</b> COOPER ET AL.	
	<b>Examiner</b> KARA NEGRELLI	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 2,3,9 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-8 and 10-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

**POROUS BODIES AND METHOD OF PRODUCTION THEREOF**

**DETAILED ACTION**

***Response to Amendment***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any rejections stated in the previous Office Action and not repeated below are withdrawn.
3. It is noted that claim 11 has been amended to included the limitation of "...said oil-in-water emulsion having a continuous phase and a discontinuous phase."
4. No new rejections have been made over previously rejected claims. For this reason it is proper to make the present action FINAL.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
6. Claims 1, 4-8, 10-11 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 5,025,004), as evidenced by Steiner et al. (US 4,888,420) and Pruss et al. (US 2003/0215502).
7. Wu et al. teach processes for forming lattice-like materials comprising 0.5% to 70% (column 4, lines 18-20) of at least one oil-in-water surfactant material (column 3,

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lines 51-55), from 5 to 35 weight percent of a material which may comprise cellulose acetate (column 4, lines 14-15 and column 6, line 11), and further comprising at least one of a UV absorber (such as 2 hydroxy-4-methoxy benzophenone or 2-ethylhexyl salicylate, which are water insoluble); fragrances such as lemon oil or orange oil (which are water insoluble materials); and/or Vitamin E derivatives such as Vitamin E succinate (of which Vitamin E succinate is a water-soluble form of vitamin E, pertaining to instant claim 8).

8. Although Wu et al. describes cellulose acetate as a water insoluble polymer, cellulose acetate materials, including cellulose acetate phthalate, may be soluble in water. See Steiner et al., column 2, lines 42-44. Furthermore, the instant specification acknowledges that cellulose derivatives which are soluble in water include cellulose acetate (see paragraphs [0071]-[0073]). Case law holds that a material and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

9. The oil-in-water surfactant material may comprise polyoxyethylene sorbitan tristearate, which is a waxy solid at room temperature with an HLB value of about 10.5 (see attached Data Sheet: Polyoxyethylene (20) Sorbitan Tristearate) (pertaining to instant claims 5-7 and 14-17).

10. The lattice-like materials of Wu et al. include dried (including freeze-dried, see column 3, line 14 and column 8, lines 12-20), powdered polymeric materials may have a particle size in the range of from 10  $\mu\text{m}$  to 30  $\mu\text{m}$  (meaning the particles are not spheres with a diameter of from 0.2 to 0.5 mm). See column 8, lines 37-39).

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11. The composition further comprises 1 to 65% of a water-in-oil emulsifying agent, which may comprise a hydrocarbon with a chain length of 18 carbons, an ester of a monoglyceride, or a sulfonated ester (see column 6, line 65 to column 7, line 20) (pertaining to instant claims 18-20).

12. In a typical freeze-drying process, a dispersion is placed in a suitable vessel and frozen (by means of a fluid freezing medium) to a temperature of about -5°C to -100°C (a temperature sufficient to rapidly freeze a liquid medium). The frozen dispersion is then subjected to reduced pressure. Under conditions of reduced pressure and reduced temperature, the frozen solvent is removed by sublimation yielding a solid, porous material. See paragraph [0111] of Pruss et al.

13. The amounts of surfactant and polymeric (cellulose acetate) material taught in Wu et al. overlap the instantly claimed ranges of surfactant and water-soluble polymeric material. The amount of hydrocarbon material of Wu et al. overlaps the ranges of instant claims 18-19. It is well settled that where the prior art describes the components of a claimed compound or compositions in concentrations within or overlapping the claimed concentrations a prima facie case of obviousness is established. See *In re Harris*, 409 F.3d 1339, 1343, 74 USPQ2d 1951, 1953 (Fed. Cir 2005); *In re Peterson*, 315 F.3d 1325, 1329, 65 USPQ 2d 1379, 1382 (Fed. Cir. 1997); *In re Woodruff*, 919 F.2d 1575, 1578 16 USPQ2d 1934, 1936-37 (CCPA 1990); *In re Malagari*, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974).

14. Wu et al. do not elaborate on the intrusion volume of the lattice-like polymeric materials of the invention. However, Wu et al. teach identical materials which may used

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in identical amounts as disclosed in the instantly claimed application. The powdered materials of Wu et al. may also be produced using a freeze-drying process, which is taught in the instant invention. One of ordinary skill in the art would therefore reasonably expect the compositions of Wu et al. to exhibit the same properties as the instantly claimed invention, including the specified intrusion volume. Case law holds that a material and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

15. The limitation of claim 1 which teaches that the "water insoluble material incorporated into said lattice to be dispersed when the water soluble porous body dissolves" is a future intended use and describes what may happen to the porous bodies of the invention when dissolved in a substance. Case law holds that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Because Wu et al. teach the same materials which may be used in the same amounts to form lattice-like polymeric material, as are taught in the instant application, it is the examiner's position that the polymeric materials of Wu et al. are not structurally different than the porous bodies of the instant invention and would therefore behave the same.

16. It is noted that while instant claim 21 claims solutions or dispersions, claim 21 is recited in the product-by-process format by use of the language, "Solutions or

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dispersions comprising water soluble polymeric materials and surfactant formed by...”

Case law holds that:

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

17. To the extent that the process limitations in a product-by-process claim do not carry weight absent a showing of criticality, the reference discloses the claimed product in the sense that the prior art product structure is seen to be no different from that indicated by the claims.

18. In addition, instant claim 21 teaches a future intended use for the porous bodies of instant claim 1. Case law holds that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

19. It is also noted that claim 1 recites the limitation of “less than 10% by weight of a water soluble material other than surfactant. The examiner notes that **less than 10%** includes 0% by weight, making this component an optional element.

20. Claims 1, 4-8, and 10-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pruss et al. (US 2003/0215502).

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21. Pruss et al. teach a composition for forming tablets, said composition of which may comprise from 0.1 to 99.9 wt% of xanthan gum (see paragraphs [0085]-[0086] and paragraph [0100]), 10 to 50 wt% of polyethylene sorbitan fatty esters or calcium stearate (which is a surfactant which is solid at room temperature) (see paragraphs [0064] and [0099]), and which may further comprise at least one of a lubricating agent, a sweetener, a flavoring agent, a preservative such as propylparaben (which is insoluble in water), and/or a diluent material (see paragraphs [0088]-[0096]). The composition may further comprise proteins, antifungals, vitamin and mineral supplements, primrose oil, and/or fish and marine animal oils (see paragraphs [0055]-[0056]). The tablets of Pruss et al. are not spherical beads having an average bead size of 0.5 to 5 mm, and the molded bodies (tablets) of Pruss have a particle size above 5 mm.

22. Blending may be accomplished by means of lyophilization. In lyophilization, the dispersion is placed in a suitable vessel and frozen to a temperature of about -5°C to about -100°C. Under conditions of reduced temperature and pressure, the frozen solvent is removed by sublimation yielding a solid, porous material (see paragraph [0111] of Pruss et al.). Pruss et al. also teach that the lyophilization process described in Erbeia (US 4,178,695) may be used and is incorporated herein by reference. Erbeia teaches that in the freeze-drying process, cooling may be controlled to produce granulated substances, such as dividing a substance into particles by means of an adapted spray nozzle or distributed by moulding or extrusion in appropriate containers and then subsequently cooling the substance (pertaining to instant claim 12).



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23. The amounts of xanthan gum, polyethylene sorbitan fatty esters or calcium stearate (which is a surfactant which is solid at room temperature) (see paragraphs [0064] and [0099]), at least one of a lubricating agent, a sweetener, a flavoring agent, a preservative such as propylparaben (which is insoluble in water), and/or a diluent material (see paragraphs [0088]-[0096]) overlap the instantly claimed ranges of water soluble polymeric material, surfactant, and water insoluble material of the instantly claimed invention. It is well settled that where the prior art describes the components of a claimed compound or compositions in concentrations within or overlapping the claimed concentrations a prima facie case of obviousness is established. See *In re Harris*, 409 F.3d 1339, 1343, 74 USPQ2d 1951, 1953 (Fed. Cir 2005); *In re Peterson*, 315 F.3d 1325, 1329, 65 USPQ 2d 1379, 1382 (Fed. Cir. 1997); *In re Woodruff*, 919 F.2d 1575, 1578 16 USPQ2d 1934, 1936-37 (CCPA 1990); *In re Malagari*, 499 F.2d 1297, 1303, 182 USPQ 549, 553 (CCPA 1974).

24. Pruss et al. do not elaborate on the intrusion volume of the polymeric materials of the invention. However, Pruss et al. teach identical materials which may used in identical amounts as are disclosed in the instantly claimed application. One of ordinary skill in the art would therefore reasonably expect the compositions of Pruss et al. to exhibit the same properties as the instantly claimed invention, including the specified intrusion volume. Case law holds that a material and its properties are inseparable. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

***Response to Arguments***

25. Applicant's arguments filed April 14, 2010 have been fully considered but they are not persuasive.

26. Applicant asserts that it is improper to refer to the "method of manufacture" description in Wu to arrive at the percentages of components in the Office Action (columns 3 to 7). Applicant argues that instead, as claim 1 is a product claim, reference should be to the description of percentages of the components in the powder in column 8, lines 20-42 of Wu et al.

27. Applicants' argument is not persuasive. It is obvious to one of ordinary skill in the art that a method of adding a series of components is going to form a product. The percentages of the "method" of Wu differ from the "powder" of Wu in that the method incorporates solvents. The instant claims do not exclude said solvents. Therefore the "method" of Wu forms compositions with the required amounts of components described in instant claim 1.

28. It is noted that the Wikipedia and enerex.ca "Enteric Coating" articles have been acknowledged. Applicant argues that because the "cellulose acetate" component of Wu is described as "water-insoluble" and because the instant specification describes "cellulose acetate" as a "water-soluble" component, the components of each respective reference are different and Wu cannot be used in an obviousness rejection of the instant claims.

29. Applicants' arguments are not persuasive. It is noted that the same polymer, cellulose acetate, is recited in both the Wu reference and the instant claims and

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disclosure. It is further noted that there is an inherent vagueness in the terms "soluble" and "insoluble" given that the solubility of a material is dependent on several factors including pH, temperature, pressure, and the nature of the solute and/or solvent, making the terms "soluble" and "insoluble" relative terms. The claims do not give describe the conditions for determining the factors listed above.

30. Because Wu et al. and the instant claims recite "cellulose acetate" for use in their respective inventions, and because the solubility parameters are not defined in the instant claims or specification, absent proper evidence, the polymers of Wu et al. are seen to be no different than the instantly claimed polymers and would therefore inherently have the same properties. An affidavit or declaration showing that the instantly claimed cellulose acetate has different solubility parameters than the cellulose acetate of Wu et al. would provide sufficient evidence to show that the cellulose acetate components of the respective references are different.

31. Applicant argues that the instant claims recite "emulsion-templating" which renders the instant invention unobvious over the claims.

32. Applicants' arguments are not persuasive. In emulsion-templating, as described in instant claim 11, an oil-in-water emulsion is formed, followed by a freeze-drying process. It is unclear how removal of a solvent prior to freeze-drying results in a product which is not "emulsion-templated" because the water-insoluble components will remain in the composition after removal of the solvent as an emulsion. Additionally, removal of the solvent is not excluded from the instant method (described in claim 11).

Furthermore, even if one were to assume that the removal of the solvent in Wu would

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result in a product which is not emulsion templated, Wu et al. teaches that the solvent removal step is optional (column 4, lines 54-59, wherein the phrase “followed by the **optional** step of removing the organic solvent).

33. Applicant argues that there is no disclosure in Wu et al. of porous bodies containing **less than 10%** by weight of a water soluble polymer other than a surfactant and the of the body having an intrusion volume of at least 3ml/g. The examiner notes that **less than 10%** includes 0% by weight, making this component an optional element. Furthermore, column 4, lines 14-20 of Wu et al. teach from 5 to 35 weight percent of a material which may comprise cellulose acetate (column 4, lines 14-15 and column 6, line 11).

34. Applicants' arguments with regards to the rejection of claims 1, 4-8, and 10-17 under 35 U.S.C. 103 (a) as being unpatentable over Pruss et al. (US 2003/0215502).

35. With regards to emulsion-templating, it is unclear how the lyophilization and subsequent freeze-drying disclosed in Pruss differs from the claimed invention. As described in the rejection above, lyophilization is a process comprising the dispersion is placed in a suitable vessel and frozen to a temperature of about -5°C to about -100°C. Under conditions of reduced temperature and pressure, the frozen solvent is removed by sublimation yielding a solid, porous material (see paragraph [0111] of Pruss et al.). Pruss et al. also teach that the lyophilization process described in Erbeia (US 4,178,695) may be used and is incorporated herein by reference. Erbeia teaches that in the freeze-drying process, cooling may be controlled to produce granulated substances, such as dividing a substance into particles by means of an adapted spray nozzle or

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distributed by moulding or extrusion in appropriate containers and then subsequently cooling the substance (pertaining to instant claim 12).

36. The composition of Pruss may comprise from 0.1 to 99.9 wt% of xanthan gum (see paragraphs [0085]-[0086] and paragraph [0100]), **10 to 50 wt%** of an active agent which can be polyethylene sorbitan fatty esters or calcium stearate (which is a **surfactant** which is solid at room temperature) (see paragraphs [0064] and [0099]), and which may further comprise at least one of a lubricating agent, a sweetener, a flavoring agent, a preservative such as propylparaben (which is insoluble in water), and/or a diluent material (see paragraphs [0088]-[0096]). The composition may further comprise proteins, antifungals, vitamin and mineral supplements, primrose oil, and/or fish and marine animal oils (see paragraphs [0055]-[0056]). The tablets of Pruss et al. are not spherical beads having an average bead size of 0.5 to 5 mm, and the molded bodies (tablets) of Pruss have a particle size above 5 mm. It is further noted that tablets (such as medicaments) are porous bodies.

37. For the reasons provided above, applicants' arguments are not persuasive.

### **Conclusion**

38. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

39. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA NEGRELLI whose telephone number is (571)270-7338. The examiner can normally be reached on Monday through Friday 9:30 am EST to 6:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571)272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/KARA NEGRELLI/

Examiner, Art Unit 1796

/RANDY GULAKOWSKI/

Supervisory Patent Examiner, Art Unit 1796